

[OPTS-42011B; TSH-FRL 2888-6].

2-Chlorotoluene: Decision Not To Test

AGENCY: Environmental Protection Agency (EPA). ACTION: Notice.

SUMMARY: EPA is issuing a decision not to require further testing of 2-chlorotoluene (2-CT, CAS No. 95-49-8) for health and environmental effects and chemical fate under TSCA section 4(a)(1)(A). Data have been received that adequately characterize 2-CT for these effects.

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Agency is publishing a decision not torequire additional testing of 2chlorotoluene for health or environmental effects or chemical fate.

L Introduction

A. Background

In the Eighth Report of the Interagency Testing Committee (ITC). the committee designated 2chlorotoinene (2-CT) for testing consideration (see the Federal Register of May 22, 1981 (46 FR 28138)). The committee recommended that 2-CT be tested for carcinogenicity, mutagenicity. chronic effects, reproductive effects, and terategenicity in mammals; for bioconcentration and chronic effects in fish and aquatic invertebrates; and for environmental fate. In the Federal Register of April 28, 1982 (47 FR 18172), EPA issued a notice of a negotiated testing agreement (NTA) between EPA and Hooker Chemical and Plastics Corp. (Occidental Chemical Corp.) for 2-CT. The testing program outlined a multitiered series of health effects tests designed to answer the concerns expressed by the ITC. In addition. Hooker agreed to test 2-CT in a set of

two acute and two chronic aquatic toxicity tests. The specific details of the NTA are presented in the April 28, 1982 Federal Register notice. The testing program developed in the NTA has been completed, and EPA has announced receipt of the test results in the Federal Register. These notices are included in the public docket for this notice.

On August 24, 1984, the U.S. District Court, Southern District of New York, ruled that negotiated testing agreements were not a legal substitute for rulemaking under section 4 of TSCA. (NRDC v. EPA, 595 F. Supp. 1255 (S.D.N.Y.) 1984). In its final order the court required that EPA publish a notice of proposed rulemaking for 2-CT or reason for not initiating rulemaking by October 1985. This notice is being published in response to the court's mandate and announces the Agency'sdecision not to require additional health. effects, chemical fate, or environmental effects testing for 2-CT.

B. Approach to Rulemaking

Under section 4(a) of TSCA, the Administrator shall by rule require testing of a chemical substance to develop appropriate test data if the Agency finds that:

(A)(i) the manufacture; distribution incommerce, processing, use, or disposal of achemical substance or mixture, or that any combination of such activities, may present an unreasonable risk or injury to health or the environment.

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture.

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

In making section 4(a)(1)(A) findings. EPA considers both exposure and toxicity information to make the finding that the chemical may present an unreasonable risk. For the second finding under section 4(a)(1)(A), EPA examines toxicity and fate studies to determine whether existing information is adequate to reasonably determine or predict the effects of human exposure to or environmental release of the chemical. In making the third finding that testing is necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's approach to determining whenthese findings are appropriately made is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) findings are discussed at FR 45 48528 and 46 FR 30300, and the section 4(a)(1)(B) findings are discussed at 46 FR-30300.

II. Profile

A. Manufacture and Use

2-Chlorotoluene (CAS No. 95-49-8) is a colorless aromatic liquid with a boiling point of 15.2° C. It has a low solubility in water, is soluble in most organic solvents and its log octanol/ water partition coefficient is 3.42 (Ref. 22).

Between 8 and 60 million pounds of 2-CT is produced annually in the United States for use as a herbicide carrier (50 percent), textile dye carrier (20 to 25 percent), general solvent (10 to 15 percent), paint stripper and general cleaner (10 percent), o-dichlorobenzene extender, and component in solvent text printing (10 percent). 2-CT is produced captively as a single isomer or as part of a mixture of monochlorotoluenes used as an agricultural solvent (Ref. 31).

B. Exposure and Release

2-CT waste generated during manufacture is incinerated, and little or no 2-CT is expected to enter ambient waters as a result of its manufacture. Monitoring data collected at the Hooker Chemical Plant in Niagara Falls, NY, by the New York Department of **Environmental Conservation (NYDEC)** indicated no 2-CT was present in the process-related effluent from the Hooker Plant (Ref. 17). However, NYDEC's survey identified 2-CT as being present in the municipal outfall, located below the falls on the Niagara River (Ref. 17). EPA estimates as much as 100 pounds of 2-CT per day may enter the Niagara River from nonprocess-related sources such as ground water contamination from agricultural or other uses. 2-CT concentrations may reach 0.10 micrograms (µg) per liter (parts per billion) at this discharge point (Ref. 17).

Chlorotoluene (unspecified isomers). has been identified in the Torresdale Water Treatment Plant, Philadelphia (1 out of 7 samples) (Ref. 26; in the Delaware River in winter, but not in summer (Refs. 19, 24, and 28); in trace quantities in drinking water around Niagara Falls and Buffalo, NY; at up to 12 µg/m³ in the air of these cities (Ref. 27); in effluent-monitoring samples from organic chemical manufacturing and plastics plants (Ref. 32); and in sedimentsamples from the Niagara River (Ref. 16). Only the NYDEC and effluentmonitoring samples specifically identify: 2-CT. The other surveys only identified the presence of monochlorotoluene and did not separate the three possible monochlorotoluene isomers. 2-CT has not been observed in ambient water samples (Ref. 25), in municipal sludge (9 cities) (Ref. 23), in air and water near industrial sites (Ref. 29), or in the Ground Water Supply survey (0.5 mg/l detection limit) conducted by EPA (see: FR 24330, June 12, 1984).

Workplace exposure to 2-CT is thought to be primarily by inhalation. Hooker (Occidental) estimated 200 workers are exposed either daily or occasionally during manufacture (Ref. 33). Hooker also estimated approximately 2,000-3,000 workers may be exposed during use of use of 2-CT (Ref. 33). Current recommended Threshold Limit Values (TLV) for 2-CT in workplace air are 50 ppm (250 mg/m³) Time-Weighted Average (TWA) and 75 ppm (375 mg/m³) Short-Term Exposure Limit (STEL) (Ref. 36).

C. Health Effects

1. Mutagenicity. No additional mutagenicity testing is being proposed because available data are sufficient to reasonably predict that 2-CT is unlikely to produce either gene mutations or chromosomal aberrations. 2-CT tested in the Ames test in strains TA-100, TA-1537, TA-1538, and TA-1535 at 0.02-1.7 µl per plate, both with and without metabolic activation, produced valid negative results (Refs. 14 and 15).

A mouse lymphoma forward mutationassay testing 2-CT's ability to induce forward mutation in both inactivated and activated mouse lymphoma L5178Y cells using 1.95 to 31.3 nl/ml and 10 to 60 nl/ml, respectively, did not produce positive results (Ref. 12).

In vitro chromosomal aberration testing of Chinese hamster ovary cells, both with and without activation, exposed to 0.083 to 833 nl/ml produced valid negative results (Ref. 10). An in vivo rat bone marrow cytogenetic assay, at 30, 100, or 300 mg/kg in five acute daily doses, produced valid negative





results (Ref. 13). A cell transformation assay without activation at 27.7 to 110.8 nl/ml also produced valid negative results (Ref. 11).

2. Developmental toxicity. No additional developmental toxicity testing is being proposed. Data developed under the negotiated testing agreement are adequate to indicate 2-CT does not cause developmental toxicity.

New Zealand White rabbits were exposed to 0, 1.5, 4, or 10 mg/l 2-CT in air, 6 hours per day, during days 6 through 28 of gestation. No significant fetal toxicity was observed even at maternally toxic doses (Ref. 4).

Rats were exposed to 6.1.3. or 9 mg/l. 2-CT in the air for 6 hours per day during days 6 through 19 of gestation. Statistically significant embryotoxicity was observed only at the maternally toxic 9 mg/l dose (Ref. 3).

3. Chronic Effects. Chronic effects testing is not being proposed.
Subchronic testing in two species, rat and dog, has been performed. In 100-day gavage studies in rats, 2-CT [20, 80 or 320 mg/kg-day] produced no treatment-related effects on survival blood. chemistry, urine chemistry, organ weights or pathology (Ref. 18). Beagles given 2-CT in capsules [5, 20 or 80 mg/kg-day] for three months were unaffected [Ref. 18].

In the range-finding study for the teratology studies cited above, rats and rabbits were exposed to 2-CT by inhalation for 14 and 23 consecutive days, respectively, for six hours per day (Ref. 37). For rats, the doses were 4.0, 7.7, 11.4, and 15.3 mg/i and for rabbits 4.0, 7.8, 11.5 and 15.6 mg/i. Both species showed dose-related weight loss. In rats only, dose-related increase in liver weight and decrease in splenic weight was observed. EPA does not believe these data indicate a need for further

chronic effects testing.
4. Reproductive Effects. Reproductive effects testing is not being proposed. The mutagenicity and developmental toxicity data received from the negotiated testing program indicate 2-ET does not induce mutagenic effects in mammalian cells, nor does it produce embryotoxic effects in rats and rabbits at nonmaternally toxic doses. There were no effects on the reproductive organs in any of the long-term tests described above, and no other evidence that exposure to 2-CT may present a reproductive hazard. Therefore, further reproductive effects testing is not being proposed.

5. Oncogenicity. Oncogenicity testing is not being proposed for 2-CT. As previously discussed, 2-CT is not mutagenic under the conditions of the studies conducted by Occidental. In

addition. Occidental submitted the results of two metabolism studies in rats (Refs. 2 and 5). In one study the rats were given oral doses of 1 mg/kg ringlabeled 2-CT, and in the other study 0.7 mg/kg ring-labeled 2-CT was injected intravenously (i.v.). In the i.v. study 14 to 18 percent of the 2-CT was exhaled unchanged; only 1-4 percent was exhaled in the oral experiment. 4CO2 was an insignificant component of the volatile metabolites in both studies, less than one percent of the applied dose in the oral study and less than 0.04 percent of the applied dose in the i.v. study. This indicates a stability of the aromatic ring to exhaustive metabolic degradation. Urinary elimination accounted for 69 to 81 percent (i.v.) and 85 to 92 percent (oral) of the original 1 C dose. Fecal elimination accounted for 5 to 8 percent (oral) and 1 to 3 percent (i.v.). The metabolites identified for the i.v. and oral studies included the mercapturic acid derivative of 2-chlorotoluene (22 to 23 percent, 21 to 28 percent), the glucuronide of 2-chlorobenzyl alcohol (13 to 20 percent, 34 to 42 percent), and 2-chlorohippurate (7 to 11 percent, 20 to. 23 percent). An unidentified polar metabolite (11 percent of urinary 14C) was also eluted with the uninary metabolites from the i.v. study (Ref. 2). Within four days, less than 1 percent of the administered dose remained in the carcass for either the i.v. or oral studies. The results from these two studies indicate that rat metabolizes 2-CT in a consistent pattern, whether it passes. through the digestive system (oral) or is introduced directly into the circulatory system (i.v.). Since the mercapturic acid was shown to derive from methyl oxidation and not ring oxidation, there are no major metabolites indentified from metabolism of 2-CT that would suggest direct-alkylating intermediates (i.e. arene oxides) and thus oncogenic potential. Although the unidentified metabolite could be a ring-oxidation product such as a phenol, such identification would be insufficient to establish an arene oxide pathway. In any case, the fact that 2-CT metabolism proceeds largely, if not entirely, via methyl oxidation and, more importantly, the lack of activity in four mutagenicity studies lead the Agency to conclude that there is no basis to find that exposure to 2-CT may present an unreasonable risk of oncogenicity. Therefore, EPA is not proposing an oncogenicity testing requirement for 2-CT.

D. Chemical Fate and Environmental Effects

Additional environmental toxicity and chemical fate testing is not needed because data received from the

negotiated testing agreement are sufficient to reasonably predict the toxic behavior of 2-CT in aquatic environments and 2-CT is not predicted to persist in the environment long enough to cause toxic effects.

2-CT is expected to enter aquatic environments as a result of its manufacture and use. The Agency predicts that volatilization is the primary route of 2-CT removal from ambient waters, with an expected volatility half-life of less than five days (Refs. 22, 34, and 35). At the current levels of release, 2-CT is expected to leave the ambient waters, producing steady-state concentrations too low to cause concern from chronic effects on aquatic organisms. EPA finds no need for further chemical fate testing at this time.

Aquatic toxicity testing provided 96hour LCIso values for trout and fathead minnows of 2.3 mg/l and 7.5 mg/l. The 96-hour NOEL's were 0.76 mg/l and 1.8 mg/l, respectively (Refs. 6 and 7). An embryo-larva test in fathead minnows provided a maximum acceptable toxicant concentration range of 1.4 to 2.9 mg/l with a NOEL of less than or equal to 1.4 mg/l (Ref. 8). Fathead minnows exposed to a measured concentration of 0.011 (\pm 0.0029) mg/l of 2-CT for 22 days reached a steady-state tissue concentration plateau within seven days. The tissue concentration of 2-CT then decreased until day 22 when exposure to 2-CT was discontinued. During the 14-day depuration phase of the study, 87 percent depuration was observed. Ninety-five percent depuration was calculated to occur at 40 to 45 days (Ref. 20). Tissue analysis of minnows at day 22 showed that 63-78 percent of the radioactivity was present as 2-CT (Ref. 21). The bioconcentration factor was calculated to be 890 \pm 340 under the conditions of this study (Ref. 1). Acute, flow-through testing of Daphnia magna at 0.33, 0.45, 0.72, 1.4, or 4.5 mg/l of 2-CT provided LC50 values of 1.0 mg/l and 1.1 mg/l at 24 and 48 hours, respectively (Ref. 9). The no-discernibleeffect-concentration through 48 hours was calculated to be 0.45 mg/l (Ref. 9). Occidental also is conducting a 21-day chronic Daphnia study. Results from this study should be available by the time this Notice is published and will be added to the public record.

III. Decision not to Initiate Rulemaking

The health effects testing submitted to the Agency by Occidental pursuant to the NTA has been reviewed. The Agency finds that these data are adequate to predict the effects on human health of activities involving 2—

CT and that additional testing need not be required at this time.

The bulk of the 8 to 60 million pounds of 2-CT produced annually in the U.S. is employed in non-consumptive uses (e.g., solvent, herbicide carrier, dye carrier) and will ultimately be released to the environment. Much of this release is expected to volatilize to air at a. relatively rapid rate. Once in the atmosphere, 2-CT is expected to be rapidly degraded by photooxidation. EPA concludes that sufficient data are available to reasonably predict the chemical fate of expected releases of 2-CT.

Monitoring data provide evidence of law (ppb) concentrations of 2-CT in some ambient waters. Although existing data show that 2-CT can be bioconcentrate in fish, EPA concludes that even allowing for such bioconcentration the levels of 2-CT likely to be achieved by aquatic species will be far too low to lead to acute or chronic toxicity. Furthermore, available data indicate that fish chronically exposed to 2-CT at a concentration of roughly 10 ppb are able to metabolically adapt and within 10 to 12 days begin to effectively remove 2-CT without effects on normal behavior. EPA therefore finds that data are sufficient to reasonablypredict 2-CT's aquatic toxicity and chemical fate and is not proposing additional environmental toxicity or chemical fate testing at this time:

IV. Public Record

EPA has established a public recordfor this decision (docker number OPTS-42011B). This record includes the background information considered by the Agency during the development of the NTA and copies of the reports submitted by Occidental Chemical Corp. pursuant to the testing program identified in the NTA.

The record includes the followinginformation:

A. Supporting Documentation

(1) Federal Register notices pertaining to this decision consisting of:

(a) Notice containing the ITC designation of 2-CT to the Priority List (48 FR 28138; May 22, 1981).

(b) Notice of request for public comment on 2-CT NTA (47 FR 3596; January 26, 1982) (Document No. 40-8235001).

(c) Notice of final action on 2-CT NTA (47 FR 18172: April 28, 1982) Document No. 40-82350021.

(d) Receipt of data notices (47 FR 36958. August 24, 1982; 47 FR 54160, December 1. 1982; 48 FR 12124, March-23, 1983; 48 FR 23132. May 4, 1983; 48 FR 34119. July 27, 1983; 48 FR 53159, November 25, 1983; 49 FR 5187.

February 10, 1984; 49 FR 18779, May 2, 1984; 50 FR 5421, February 6, 1985).

(e) Notice of proposed rulemaking for-National Primary Drinking Water Regulations: Volatile Synthetic Organic Chemicals (49 FR 24330; June 12, 1984).

(2) Communications consisting of:

(a) Written public and intra-agency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Summaries of meetings.

(d) Reports—published and unpublished factual materials, including contractors' reports.

B. References

(1) Springborn Bionomics, Inc. "Accumulation and elimination of 14Cresidues by fathead minnows (Pimephales. promelas) exposed to 14C-2-Chlorotoluene." January 1984 (Document #40-8435119).

(2) Zoecon Corp. "Metabolism of 2-Chloro[U-Ring-14C] toluene by rats intravenously." October 13, 1983. (Document

#40-8335096).

-(3) Huntingdon Research Centre. "Effect of 2-chlorotoluene vapor on pregnancy of the rat" (Final). August 6, 1983 (Document #40-8335095).

(4) Huntingdon Research Centre. "Effect of-2-chlorotoluene vapor on pregnancy of the New Zealand White Rabbit." (Final). August 3, 1983 (Document #40-8335094);

(5) Zoecon Corp. "2-Chlorotoluene metabolism by rats." January 14, 1983/ (Document #40-8335077).

(6) EG&G Bionomics. "Acute toxicity of ochlorotoluene to rainbow trout (Salmo gairdneri)." June 1982 (Document #40-8235089).

[7] EG&G Bionomics: "Acute toxicity of ochlorotoluene to fathead minnow (Pimephales promelas)." June 1982. (Document #40-8235068).

(8) EG&G Bionomics. "The toxicity of ochlorotoluene to fathead minnow (Pimephales promelas) embryos and larvae." July 1982 (Document #40-8235090):

(9) EG&G Bionomics. "Acute toxicity of ochlorotoluene to water flea (Daphnia

magna)." July 1982 (Document #40-8235069).
[10] Litton Bionetics, Inc. "Mutagenicity evaluation of ortho-chlorotoluene in an in vitro cytogenetic assay measuring chromosome aberration frequencies in Chinese hamster ovary (CHO) cells." (Final-Report). June 1982 (Document #40-8235064).

(11) Litton Bionetics, Inc. "Evaluation of ortho-chlorotoluene in the in vitro transformation of BALB/3T3 cells assay." (Final Report). June 1982 (Document #40-

82350661.

(12) Litton Bionetics, Inc. "Mutagenicity evaluation of ortho-chlorotoluene (OCT) in the Mouse Lymphoma Forward Mutation Assay." (Final Report). July 1982 (Document #40-8235071).

(13) Litton Bionetics, Inc. "Mutagenicity Evaluation of ortho-Chlorotoluene (OCT) in the Rat Bone Marrow Cytogenetic Assay. (Final Report). July 1982 (Document #40-

[14] Litton Bionetics, Inc. "Mutagenicity

evaluation of ortho-chlorotoluene in Ames Salmonella/ microsome Plate Test." (Final Report). March 1982 (Document #40-8235088).

(15) Litton Bionetics. Inc. "Mutagenicity evaluation of ortho-chlorotoluene (OCT). A composition of 2-chlorotoluene (96.5 percent). 4-chlorotoluene (3.4 percent), and toluene (0.1 percent) in the Ames Samonella/microsome plate test: amendment to the Final Report." April 1982 (Document #40-8235088).

(16) Rockwell, D.C., R.E. Claff, and D. Kuel. 1981 Buffalo, New York, Area Sediment Survey (BASS). U.S. Environmental Protection Agency. April 1984 (Document

#40-8435122).

(17) EPA Internal Memorandum from:R. Speed. Region II Office, to J. Heim. Headquarters. Draft Report Niagara River Toxica Project Report. September 7, 1984 (Document #40-8435123).

(18) Hill, R.M. "The safety evaluation of ochlorotoluene." Elanco Products Company. August 12, 1981 (Document #40-8135055).

(19) Sheldon, L.S. and R.A. Hites. "Source and movement of organic chemicals in the Delaware River." Env. Sci. & Tech. 13(5): 578-579. May 1979. (Document #40-7935021).

(20) Springborn bionomics. Inc. "Reply to EPA Test Rules Development Branch interrogatories (April 18, 1984) -accumulation and elimination of 14-C residues in fathead minnows, Pimephales promelas, exposed to-14—C.2-chlorotoluene." (Received June 29. 1984). Springborn Bionomics, Inc., Report No. 84-1-1535. U.S. Environmental Protection: Agency, Washington, D.C., September 5, 1984.

(21) Skinner, W.S., G.B. Quistad, and D.A. Schooley: "Metabolism of [14-C]-2-Chlorotoluene by fathead minnows." Zoecon Corp., September 18, 1984.

(22) Occidental Chemical Corp. Letter: Sam:

Gelfand to John Helm, U.S. Environmental Protection Agency, Washington, D.C. January

(23) Erikson, M.D., and E.D. Pellizzari. "Identification and analysis of polychlorinated biphenyls and other related chemicals in municipal sewage sludge samples." EPA 560/6-77-021. EPA. Washington, D.C. 1977.

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(25) Hushon, J., R. Clermin, R. Small, S. Sood, A. Taylor, and D. Thomas. "An assessment of potentially carcinogenic energy-related contaminants in water." Published by the Mitre Corp., for the U.S. Department of Energy and the National Cancer Institute. 1980.

(26) Jungclaus, G.A. Lopez-Avila, V., and Hites, R.A. Env. Sci. & Tech., 12: 88-96, 1978.

(27) Pellizzari, E.D., M.D. Erickson, and R.A. Zweidinger. "Formulation of a preliminary assessment of halogenated organic compounds in man and environmental media." EPA 560/13-79-006. EPA. Washington, D.C. 1979.

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Letter from D.J. Boundy, Hooker Chem. to R.
Tadvarthy, Mathematica, Inc. Response to
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Development Branch, Washington, D.C. June
25, 1987 (Document #40-8135048).

(32) USEPA Telephone Contact: John Helmto Walt Shakelford. Presence of 2chlortoluene in ambient waters. January 14.

(33) Hooker Chemicals and Plastica.
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(34) Occidental Chemical Corporation.
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(35) USEPA. U.S. Environmental Protection Agency, Computer Printout (EXAMS). Exposure analysis modeling system—V2.0: Mod. 1. Ecosystem River 100 CFS, Chemical: 2-Chloroteluene: Retrieved January, 1985. Washington, D.E., Test Rules Development Branch, 1985.

(38) AGCIH: American Conference of Governmental Industrial Hygienists. o-Chlorotoluene. Threshold limit values for chemical substances in work room air. pg. 95– 96. 1984.

(37) Huntingdon Research Centre. "2-Chlorotohene, a preliminary inhalation study in the rat and rabbit." January 13, 1983 [Document #40-8335092].

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, will be made available for inspection in the OPTS Reading Room, Rm. E-107, 401 M St., SW., Washington, D.C. from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Agency will supplement the record periodically with additional relevant information received.

(15 U.S.C. 2003)

Dated: September 27, 1985.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances
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